Supreme Court, U.S.
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No. 92-303

IN THE

Supreme Court of the United States

OCTOBER TERM, 1992

ALBERT SLATER,

Petitioner,

vs.

OPTICAL RADIATION CORPORATION,

Respondent.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Seventh Circuit

RESPONDENT'S BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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TABLE OF CONTENTS

	PAGE
TABLE OF AUTHORITIES	ii
REGULATORY PROVISIONS INVOLVED	2
REASONS FOR DENYING THE PETITION ...	3
I.	
THE DECISION IN THIS CASE WAS CORRECT AND IS IN ACCORD WITH THE POLICIES UNDERLYING THE PREEMPTION DOCTRINE ...	3
II.	
THERE IS NO ISSUE REGARDING INFORMED CONSENT IN THIS CASE	9
III.	
THE PETITION ATTEMPTS TO ARGUE ISSUES PREVIOUSLY CONCEDED BELOW BY PETITIONER'S COUNSEL	10
IV.	
THE DECISION IN THE CASE AT BAR IS FULLY CONSISTENT WITH THIS COURT'S DECISION IN *CIPOLLONE* AND THE OTHER CASES CITED BY PETITIONER	11
CONCLUSION	19

TABLE OF AUTHORITIES

Cases

PAGE

Distinguished:

Cipollone v. Liggett Group, Inc., 112 S.Ct. 2608 (1992) ..... *passim*

Mitchell v. IOLAB Corp., 700 F.Supp. 877 (E.D. La. 1988) 9

Moore v. Kimberly-Clark Corporation, 867 F.2d 243 (5th Cir. 1989) 15

New Jersey Guild of Hearing Aid Dispensers v. Long, 384 A.2d 795 (N.J. 1978) 17, 18

Smith v. Pingree, 651 F.2d 1021 (5th Cir. 1981) .. 16

Statutes and Regulations

21 U.S.C. §360j(g) 5

21 U.S.C. §371(a) 3

21 C.F.R. §§801.1(b)(d) 4

21 C.F.R. §808.1(b) 2, 14

21 C.F.R. §813 ..... 4, 5

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Respondent Optical Radiation Corporation respectfully requests that this Court deny the Petition for Writ of Certiorari seeking review of the judgment of the United States Court of Appeals for the Seventh Circuit, reported at 961 F.2d 1330 (1992).

REGULATORY PROVISIONS INVOLVED

21 C.F.R. §808.1(b) provides:

> Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 18, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision) which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

REASONS FOR DENYING THE PETITION

Plaintiff's Petition for Certiorari should be denied. It does not demonstrate the presence of any of the factors traditionally considered important by this Court in determining that further review of a case beyond that already provided by the United States Court of Appeals is necessary.

The decision of the Court of Appeals in this case was grounded directly upon the applicable law and public policies underlying the doctrine of federal preemption. The unanimous opinion gave full consideration to Petitioner's arguments and carefully reviewed and applied the law to this case. The decision is in accord with decisional law and is not in conflict with any existing decisions. No further review of this case is warranted.

I.

THE DECISION IN THIS CASE WAS CORRECT AND IS IN ACCORD WITH THE POLICIES UNDERLYING THE PREEMPTION DOCTRINE.

The United States Court of Appeals decided in this case that Petitioner's suit for an injury to his eye allegedly caused by Respondent Optical Radiation Corporation's intraocular lens was preempted by federal law.

The Court noted that the Medical Device Amendments of 1976 to the Food, Drug and Cosmetic Act ("FDCA") gives the FDA comprehensive regulatory authority over medical devices. The Amendments authorize the agency to promulgate implementing regulations (21 U.S.C. §371(a)). The Amendments forbid states to subject a medical device to any requirement that is different from, or in addition

to, any federal requirement applicable to the device, and which relates to its safety and effectiveness, or to any other matter included in a requirement applicable to the device. The Court further observed that the FDA has declared that preemption of state requirements (whether the state is acting by statute, ordinance, regulation or court decision) is limited to cases in which the FDA has established specific counterpart regulations to the challenged state requirements or there are other specific requirements applicable to a particular device under the federal act (21 C.F.R. §§801.1(b)(d)) (Pet. p.2a).

The FDA subsequently issued "Investigational Device Exemption Regulations" for intraocular lenses (21 C.F.R. §813). These exemptions are intended to encourage innovation by exempting promising experimental devices from the usual requirement of establishing the safety and efficacy of a medical device before it can be sold. The Court observed that Congress expected the FDA to grant an investigational device exemption for intraocular lenses because the Medical Device Amendments specifically require the FDA to make such lenses reasonably available to physicians if an investigational exemption is granted (Pet. p.3). The lens involved in the case at bar received an investigational device exemption (Pet. p.3a).

Petitioner consented to participate in the clinical investigation of the experimental lens and was informed that the purpose of the study (monitored by the Food and Drug Administration) was to establish facts about the safety and efficacy of the lens (Pet. p.10a). Subsequently, when his eye was allegedly injured, Petitioner filed suit complaining of inadequate clinical testing, defective design

of the intraocular lens, and failure to warn the public of the dangers of the lens.[1]

The District Court examined Petitioner's Complaint and carefully reviewed the law pertaining to federal preemption. The Court noted that the Investigational Device Exemption regulations (21 C.F.R. §813 *et seq.*) establish rules for the investigational use of intraocular lenses as permitted by 21 U.S.C. §360j(g) (allowing the FDA to exempt investigational devices). The District Court noted that the intraocular lens IDE regulations are quite extensive. It noted that they set forth in great detail the procedures and conditions under which intraocular lens manufacturers may be granted exemptions from the safety and effectiveness requirements of the FDCA (Pet. p.16a). The District Court concluded that the Investigational Device Exemption Regulations for intraocular lenses expressly preempt state law claims based on safety or effectiveness of a particular intraocular lens, where that lens has been granted an investigational device exemption by the FDA (Pet. p.15a).

Petitioner contended in the Court of Appeals that the FDCA regulations imposed no requirements concerning the design of intraocular lenses and, therefore, that there was no preemption of state products liability law relating to design defects (Pet. p.4a). The Court of Appeals rejected this argument on the ground that Petitioner erroneously assumed that a regulation would have to actually specify a design in order to have preemptive effect. The

[1] Petitioner did not challenge the validity of the regulations themselves, did not assert that the appropriate procedures for obtaining an investigational exemption were not followed, and did not claim that the experiments were improperly conducted (Pet. pp. 2a, 5a).

Court stated that, in fact, a design could not be specified because the device was still experimental. The Court stated in part (Pet. p.5a):

> The argument assumes that the only federal requirement that might relate to the safety or effectiveness of the design of a medical device would be an actual specification of that design. The preemption provision does not say this, and so cramped an interpretation would cripple the exemption for investigational devices. The FDA can hardly be expected to specify the safe and effective design of a device when it is still experimental. If there were a known safe and effective design, the device would no longer be experimental. The point of the experiment is to find out whether it is safe and effective. *Public Citizen Health Research Group v. FDA*, *supra*, 704 F.2d at 1283. In the experimental phase the appropriate regulations of safety and effectiveness are procedural rather than substantive ones. They do not specify the safe and effective design; they specify the procedures for determining whether the experimental design is safe and effective. These are requirements relating to safety and effectiveness and they can therefore have preemptive effect.

The Court further stated that Petitioner's theory was, in effect, that the design of the lens was not sufficiently safe and effective to be used on human beings. It found that this theory was in direct conflict with the federal policy expressed in the MDA and the IDE regulations allowing the experiments to go forward. The Court stated (Pet. p.5a):

> Of course the FDA will not grant an investigational-device exemption unless it believes that the device has sufficient promise of being proved safe and effective to justify the risk of its being used on human beings. Although that belief is different from a certification that the design of the device is safe and

> effective, it is a certification that the design is sufficiently safe and effective to allow experimental use on human beings. The theory underlying the complaint is that the design of the Stableflex was not sufficiently safe and effective to allow it to be used on human beings. This theory sets up a direct collision with federal policy. The FDA decided, whether rightly or wrongly, but pursuant to regulations the validity of which the plaintiff does not question, that Stableflex could be sold, subject only to requirements, procedural in character and, so far as appears, fully complied with, designed to assure that this experimental distribution was in fact a worthwhile experiment. The plaintiff wishes in the name of state tort law to impose additional requirements—namely that Stableflex have had design characteristics that it lacked—and this engrafting of additional requirements relating to safety or effectiveness is forbidden by the preemption provision in the Medical Devices Amendments.

The Court concluded that the suit was barred by the preemption provision of the Medical Devices Amendment and thus affirmed the judgment of the District Court.

Contrary to Petitioner's suggestions that this decision adopts a broad concept of preemption, the decision is, in fact, very limited in scope. The Seventh Circuit did not make any broad proclamations regarding the general doctrine of federal preemption. It did not comment upon or disagree with any holdings of this Court or the United States Courts of Appeals relating to the subject of preemption. It simply and directly dealt with the narrow issues presented to it: i.e., whether Petitioner's asserted claims were preempted by the investigational device exemption. The Court held that the claims were preempted because the regulations specify the procedures for deter-

mining whether the experimental design is safe and effective and that these regulations have preemptive effect (Pet. p.5a).

The Seventh Circuit stated that the scope of the preemption is limited (Pet. p.6a). It is limited to efforts by states to impose sanctions for compliance with federal regulations relating to the safety or efficacy of the experimental lens. The Court stated that it does not affect cases charging negligence in the implantation or removal of a lens, or complaining of contamination of the lens by bacteria or fungi, or of failure to obtain the patient's informed consent to the procedure (Pet. p.6a). It stated that it is not the sort of blanket preemption found in ERISA. The Court noted that the limited scope of the preemption explains the prohibition incorporated by reference in the investigational-device exemption for intraocular lenses (Pet. p.7a). The prohibition preserves the patient's common law rights outside of the limited scope of the preemption provision (Pet. p.7a). The Court further observed that even within the scope of the preemption there is an important qualification: the risks of the experimental procedure must be adequately explained to the patient (Pet. p.7a). The tort law of medical battery, which is violated when an operation is performed without the patient's consent, is not preempted (but Petitioner made no such claim in this case).

This decision is notable for the widespread *agreement* of the judges regarding the propriety of the ruling. The district court judge (Paul E. Plunkett) gave this case extended consideration and in a comprehensive opinion found that Petitioner's particular claims were preempted by federal law. The United States Court of Appeals judges (Richard A. Posner, Daniel A. Manion, and Thomas E. Fairchild) unanimously held in a thorough and well-reasoned opinion

that the claims were preempted by federal law. The same judges were asked to reconsider, but again reaffirmed their judgment by their denial of rehearing. Petitioner also requested a rehearing en banc and none of the active judges requested a vote on the suggestion for rehearing en banc. This case has received due consideration and the unanimity of judgment on this case indicates that no further review is warranted.

II.

THERE IS NO ISSUE REGARDING INFORMED CONSENT IN THIS CASE.

As noted in the previous section, Petitioner was fully aware that he was voluntarily participating in an experimental study monitored by the Food and Drug Administration. Petitioner has never contended to the contrary in either the District Court or the Court of Appeals.

Petitioner wrongly states in the "Question Presented" section that a question is raised in this case regarding the fact that the FDA has by regulation barred any manufacturer of any investigational device from obtaining the patient's release from liability (Pet. p.1). Petitioner later in the Petition cites irrelevant informed consent provisions in the section "Regulatory Provisions Involved" (Pet. pp. 3-4). Petitioner also erroneously claims that the district court decision in *Mitchell v. IOLAB Corp.*, 700 F.Supp. 877 (E.D. La. 1988) (a case dealing with informed consent and construing 21 C.F.R. §50.20) is in conflict with the holding in the case at bar (Pet. pp.21-23).

None of these assertions are accurate. Petitioner did not raise these arguments in the trial court. The District Court did not decide any issue relating to informed consent. In fact, the District Court expressly distinguished the deci-

sion in *Mitchell* on the ground that it involved issues of informed consent while the case at bar did not (Pet. p.16a, n.9).

Petitioner's Brief on Appeal contained no argument relating to this issue and the Seventh Circuit Court of Appeals recognized this omission (Pet. p.7a):

> We do not understand Slater to be arguing that he did not give his informed consent to the implantation. The consent form that he signed adequately discloses the medical risks of the procedure. True, it does not indicate that by signing the form he will be giving up any legal rights. It says, "I understand that in the event of physical injury resulting from this clinical study, there is no compensation available from Hinsdale Sanitarium and Hospital [where the cataract operation and lens implantation were performed] for such injury." This could be taken to imply that of course the signator is not waiving any right to seek compensation for the manufacturer of the lens for having designed or manufactured it defectively. *But Slater has made nothing of this, either in our court or in the district court.* (Emphasis added.)

The Seventh Circuit properly limited its decision to issues raised by the parties (which did not include informed consent).

III.

THE PETITION ATTEMPTS TO ARGUE ISSUES PREVIOUSLY CONCEDED BELOW BY PETITIONER'S COUNSEL.

The Petition claims that certain matters are still "in issue" even though they had been abandoned by Petitioner's counsel. Although Petitioner now raises a broad challenge to the doctrine of federal preemption of common law damage claims, Petitioner's counsel, in fact, con-

ceded at the oral argument that certain types of preemption were valid. This was noted by the Seventh Circuit Court in its opinion (Pet. p.4a):

> The plaintiff's counsel wisely conceded at argument that insofar as the complaint might be construed to allege that Illinois tort law required the defendant to do more or different clinical testing of Stableflex than required by the FDA's regulations governing the investigational exemption for intraocular lenses, the suit is indeed preempted; for it would then be unquestionably a matter of imposing in the name of state law a different requirement relating to safety and effectiveness from that imposed by federal law.

The Court noted that Petitioner was instead asserting a claim of defective design. The scope of the issues actually preserved for review is much narrower than the Petition suggests.

IV.

THE DECISION IN THE CASE AT BAR IS FULLY CONSISTENT WITH THIS COURT'S DECISION IN *CIPOLLONE* AND THE OTHER CASES CITED BY PETITIONER.

The recent decision of this Court in *Cipollone v. Liggett Group, Inc.*, 112 S.Ct. 2608 (1992) was issued after the decision in the case at bar, but the two decisions are completely consistent.

This Court in *Cipollone* reaffirmed the general principles of the law of federal preemption. It stated that Article IV of the Constitution provides that the laws of the United States shall be the supreme law of the land and that state law that conflicts with federal law is "without effect" [112 S.Ct. at 2617]. The purpose of Congress is the ultimate touchstone of preemption analysis. Congress' intent may be explicitly stated in the statute's language

or implicitly contained in its structure and purpose [112 S.Ct. at 2617].

The Petitioner in *Cipollone* contended that the language of the Public Health Cigarette Smoking Act of 1969 which states that "no requirement or prohibition based on smoking and health shall be imposed under State law" did not preempt any common law actions. The Court rejected this argument as contrary to the plain language of the Act and the general understanding of common law damages actions. The Court stated in part [112 S.Ct. at 2620]:

> We disagree; such an analysis is at odds both with the plain words of the 1969 Act and with the general understanding of common law damages actions. The phrase "[n]o requirement or prohibition" sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common law rules. As we noted in another context, "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy. (citation omitted).
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> * * *
>
> Moreover, common law damages actions of the sort raised by petitioner are premised on the existence of a legal duty and it is difficult to say that such actions do not impose "requirements or prohibitions." See W. Prosser, Law of Torts 4 (4th ed. 1971); Black's Law Dictionary 1489 (6th ed. 1990) (defining "tort" as "always [involving] a violation of some duty owing to plaintiff"). It is in this way that the 1969 version of §5(b) differs from its predecessor: Whereas the common law would not normally require a vendor to use any specific *statement* on its packages or in its advertisements, it is the essence of the common law to enforce duties that are either affirmative *re-*

> *quirements* or negative *prohibitions*. We therefore reject petitioner's argument that the phrase "requirement or prohibition" limits the 1969 Act's pre-emptive scope to positive enactments by legislatures and agencies.

The Court further rejected Petitioner's argument that the phrase "imposed under state law" does not include common law actions. The Court stated that it has recognized that the phrase "state law" includes common law as well as statutes and regulations [112 S.Ct. at 2620].

Petitioner Slater in the case at bar concedes that a reference to "a requirement . . . under state law" may in some circumstances include common law claims (Pet. p.18). Petitioner also concedes that "a requirement" under §360k(a) may include a judicial order (such as the enforcement or the interpretation of a state law or regulation concerning devices) (Pet. p.18).

Petitioner Slater erroneously argues that read most naturally, §360k(a) concerns state and local statutes, ordinances, and regulations that impose affirmative requirements on device manufacturers (Pet. p.19). This is clearly contrary to the words of the statute and regulations. The act (§360k(a)) states that no state may establish or continue in effect with respect to a device intended for human use any "requirement" different from or in addition to an FDA requirement applicable to the device and which relates to the safety and effectiveness of the device (Pet. p.2). As noted in *Cipollone*, the term "requirement" may certainly be read to include common law damage actions.

The claim by Petitioner that the FDA has indicated that tort-like remedies are not preempted is likewise contrary to the words of the regulations. In 21 C.F.R. §808.1(b) it is provided that:

> Section 521(a) of the act [21 U.S.C. §360k(a)] contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that . . . no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance regulation, *or court decision*) which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act. (Emphasis added)

The above provision plainly refutes Petitioner's assertion. The express reference to "court decision" indicates that common law claims are included within the scope of the preemption.

This Court in *Cipollone* held that it must fairly—but in light of this strong presumption against preemption—narrowly construe the precise language of preemption and then must look to each of the petitioner's claims to determine whether it is in fact preempted. The decision in the case at bar meets this test. As the Court of Appeals noted, Petitioner's complaint was in essence one of defective design[2] and sought to impose additional requirements—design characteristics that the lens allegedly lacked (Pet. p.5a). This attempt to engraft additional requirements relating to safety or effectiveness is foreclosed by

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[2] Petitioner asserted no express warranty claims in this case such as were discussed in *Cipollone*. His implied warranty claim related to the safety and effectiveness of the device as noted by the District Court (Pet. p.15a).

the language of the statute forbidding states to subject a device to any requirement in addition to those in the Amendments (§360k(a)).

The decision in the case at bar is in full accord with this Court's decision in *Cipollone*. No conflict exists and no further review is warranted on this basis.

The Petition asserts that the lower federal courts are deeply split over the preemptive reach of the Medical Device Amendments (Pet. p.9). This is demonstrably untrue. The Seventh Circuit opinion did not note any conflict in the circuits but instead expressly stated that this case was one of first impression at the U.S. Court of Appeals level. Thus, there is no split in the federal appellate decisions.

Petitioner claims that the decision in this case conflicts with that rendered in *Moore v. Kimberly-Clark Corporation*, 867 F.2d 243 (5th Cir. 1989). This is obviously untrue. The District Court in this case was well-aware of the decision in *Moore* and in fact expressly "borrowed" the discussion of the relevant statutes, regulations and legislative history of the Medical Device Amendments from what the District Court called a "well-reasoned" opinion (Pet. p.13a). The District Court further found that decision (and other similar ones) to be inapplicable to the case at bar (Pet. p.16a, n.9):

> We find the analysis of those cases to be inapplicable here. There is no equivalent of the Investigational Device Exemption Regulations of intraocular lenses for tampons. The Medical Device Amendments to the FDCA expressly preempts state tort claims based on tampon labeling and warning, but not design. The intraocular lens IDE regulations expressly preempt all aspects of intraocular lenses safety and effectiveness.

The decision in *Moore* held that the Medical Device Amendments to the FDCA expressly preempt state tort law

claims based on tampon labeling and warning, but not design. The U.S. Court of Appeals affirmed the trial court's decision dismissing the plaintiff's state law claims based on inadequate warning and labeling. The distinction made by the District Court in this case is correct and there is no conflict in these decisions.

Petitioner erroneously claims that the Seventh Circuit in this case "disagreed" with the decision in *Moore* (Pet. p.13, n.2). The *Moore* decision is mentioned only once in the Seventh Circuit's opinion. It is in the context of a mere acknowledgement of Petitioner's argument and the fact that Petitioner relied upon *Moore* in support of his argument (Pet. p.4a). The Seventh Circuit responded that the Petitioner's argument was without merit, but did not in any way criticize or depart from the holding in the *Moore* decision.

Petitioner claims that the ruling in this case is at odds with the decision of the Fifth Circuit Court of Appeals in *Smith v. Pingree*, 651 F.2d 1021 (5th Cir. 1981) (a case not previously cited by Petitioner). This is clearly incorrect. The *Smith* decision involved a question as to whether a state statute regulating the subject of hearing aids (i.e., the fitting of, the requirement of a receipt, and the requirement of warnings on the package) was preempted by federal regulations. The Court of Appeals affirmed the district court's holding that the federal regulations did not address the areas covered by the statute and thus the state statute was not preempted. With respect to the manner of fitting the hearing aids, the Court stated that because the federal regulations did not address the mechanics of fitting hearing aids to patients, the state was free to prescribe minimal procedures to be followed and equipment to be used in the fitting of hearing aids (651 F.2d 1024). The Court also held that with respect to the

requirement of a receipt, the Florida statute did not relate to a matter included in a federal requirement applicable to a device and therefore was not preempted by the federal regulation. The Court found the receipt requirement totally unrelated to the federal statute. The Court further held that the state requirements requiring a disclaimer were different from the areas covered by the federal requirements and thus were not preempted.

The *Smith* decision has no bearing on the case at bar. The subject matter is different. The areas covered by the federal regulations and the state statute were not overlapping and the Court held that there was no preemption because there was no conflict. None of the issues raised relate to the specific questions addressed by the Seventh Circuit in the case at bar. The decisions are not in conflict.

To the extent that Petitioner was referring to federal district court decisions in asserting conflicts in the federal courts, it must be noted that the Seventh Circuit did not state that its ruling was contrary to any decided case. The reference to the *Mitchell* case (involving informed consent) and the statement that the district court disagreed with it has already been discussed above. In any event, the Court of Appeal's holding was not contrary to the holding in *Mitchell*.

Petitioner cites the decision in *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795 (N.J. 1978) (a case involving hearing aids) and states that the New Jersey Supreme Court chose to follow the conclusion of the FDA in an advisory opinion because there were no compelling indications that it was wrong. This is a mischaracterization of the holding of the Court. Although the Court did mention an advisory opinion, it expressly stated

that it reached its decision wholly apart from any deference to the FDA's opinion (384 A.2d at 810). The Court concluded that the Federal Food Drug and Cosmetic Act section expressly preempting nonfederal regulation of medical devices intended for human use expressly envisioned supplemental state regulation thus permitting a wide variety of state regulations (such as the ones involved in that case) to remain unaffected.

The *Long* case does not deal with the same federal regulations at issue here and is not pertinent to the case at bar. Moreover, Petitioner in the case at bar cited no opinion by the FDA on the IDE regulations relating to intraocular lenses.[3]

The decision in the case at bar is not in conflict with the decisions cited by Petitioner.

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[3] Although Petitioner includes in the appendix to his Petition (pp. 18-19) a purported advisory opinion relating to a different case, this letter is not only irrelevant but was not cited or shown to the District Court and was not included in the record before the U.S. Court of Appeals. In any event, such an opinion letter from the Commissioner may be revoked or amended at any time after it has been issued and stands only if it is not repudiated by the agency or overruled by a Court.

CONCLUSION

The decision in the case at bar was correct. It is in complete accord with this Court's decision in *Cipollone* and with existing federal and state decisions dealing with the preemption doctrine. Petitioner's claims regarding the need for further review are without merit.

For the foregoing reasons, the Petition for a Writ of Certiorari should be denied.

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